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MAY 2 3 2000

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Submitter

Name:	Cardiac Telecommunications	or	Delphi Consulting Group
Address:	17448 Highway 3, Ste. 175 Webster, Texas 77698 USA		P. O. Box 932 Stafford, Texas 77047
Telephone Number:	(281) 332-7587		(713) 723-8169
Contact Person:	Karim Alhussiny, Ph.D.		J. Harvey Knauss (as Regulatory Consultant
Date Prepared:	2/17/00		to Cardiac Telecommunications)

2. Device

Proprietary name:	CardTel, Model NT-100
Common name:	ECG
Classification name:	Electrocardiograph

3. Classifications Names & Citations:

21 CFR 870.2340 Electrocardiograph
21 CFR 870.2910 Radiofrequency Physiological signal transmitter and receiver

3. Predicate Device

Burdick Eclipse Plus, Burdick, Inc., K946281

4. Description

The CardTel Model NT-100 provides a portable device to continuously monitor ambulatory patient 12 lead electrocardiographic (ECG) data. The unit is designed to acquire and display up to twelve ECG vectors in a standard diagnostic ECG analysis format. The twelve leads consist of the standard twelve ECG leads, I, II, III, aVR, aVL, aVF, V1 and V6. The Model NT-100 is used to monitor patients in the operating room, recovery rooms, intensive care units, in the emergency room, in research settings, or other units where additional ECG leads are desired and real time display is desired. The display unit consists of a generally available Pentium® based personal computer or laptop computer with a SVGA monitor and color printer.

The system provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events.

5. Indications for use

The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

6. Contra-indications

May only be operated by trained personnel.

7. Comparison

The CardTel NT-100 ECG System has the same device characteristics as the predicate device, except the predicate device does not have wireless capability.

8. Test Data

The Model NT-100 System has been subjected to extensive safety and performance testing prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. The ECG Analysis system meets the specified clinical output data requirements of the ANSI/AAMI EC38-1994 specification for ambulatory electrocardiography. Standard databases have been used for automated ECG algorithm verification testing. Safety tests have further been performed to ensure the system complies to applicable industry and safety standards.

The NT-100 device labeling includes instructions for safe and effective use. It includes warning, cautions, and guidance for installation and maintenance.

9. Literature Review

A review of literature pertaining to the safety of electrocardiographs has been conducted. Appropriate safeguards have been incorporated in the design of the NT-100 unit.

10. Conclusions

The conclusion drawn from these tests is that the Model NT-100 ECG System is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2000

Cardiac Telecommunications
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K000609
CardTel, Model NT-100
Regulatory Class: II (two)
Product Code: 74 MWJ
Dated: February 16, 2000
Received: February 23, 2000

Dear Mr. Knauss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Milhern

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K000609

Device Name: CardTel Model NT-100

Indications for use: The CardTel Model NT-100 is intended to be used under the supervision of a licensed Healthcare practitioner. The Model NT-100 is intended to be used to display, record and transmit ECG signals from surface electrodes. The device is intended to acquire, display and record real time electrocardiographic information from relevant populations.

Prescription Device: Federal Law (US) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular Respiratory,
and Neurological Devices
510(k) Number K000609

Prescription Use Yes OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)